entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The above-mentioned booklet and leaflets subsequently were destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3770. Supplement to notices of judgment on drugs and devices, No. 3652. U. S. v. Woodard Laboratories, Inc., and Dean D. Murphy and John L. Sullivan. Judgment of trial court affirmed on appeal. (F. D. C. No. 30053. Sample Nos. 29794–K, et al.)

Following the imposition of the sentences against the defendants, as reported in notices of judgment on drugs and devices, No. 3652, an appeal was taken by the defendants to the United States Court of Appeals for the Ninth Circuit. On August 29, 1952, the following opinion was handed down by that court, affirming the judgment of the lower court:

ORR, *Circuit Judge:* "This is an appeal from judgments of conviction on an information charging appellants with violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 301 et seq. Appellant Woodard Laboratories packaged and shipped in interstate commerce certain drugs manufactured by Crest Laboratories. Appellants Murphy and Sullivan are, respectively, president and general manager of Woodard Laboratories. The information charged the appellants in ten counts with five interstate shipments of alpha-estradiol tablets whose strength was below that declared on the labels; each shipment was the basis for two counts; one relating to adulteration and one to misbranding. 21 U. S. C. A. §§ 331 (a), 351 (c), and 352 (a). The District Court, sitting without a jury, found each of the defendants guilty on the five counts relating to adulteration. A total fine of $2500 was imposed upon Woodard and a total fine of $500 was imposed on each of the individual defendants.

"The tablets in question are shipped under the trade name 'Estrocrine' and contain alpha-estradiol, a female sex hormone which is dispensed only by or on the prescription of a physician. Samples of the tablets were subject to laboratory analysis by the Food and Drug Administration; the results of these assays led directly to the filing of the information. A drug distributor has an absolute liability for adulterated and misbranded drugs that he introduces into interstate commerce. 'Balancing relative hardships, Congress has preferred to place it on those who have at least the opportunity of informing themselves of the existence of the conditions imposed for the protection of the consumers before sharing in the illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.' United States v. Dotterweich, 320 U. S. 277, 285 (1943). The appellants contend, however, that the evidence was insufficient to sustain the judgment. A determination of this question requires a brief summarization of the evidence.

"Two witnesses testified for the Government. They are outstanding authorities in the general field of pharmaceutical chemistry and both have had a large experience in the study of estrogenic hormones.[1] They described in detail the methods of assay used in determining whether the Woodard tablets contained the 22 mcgs. of alpha-estradiol their labels represented the tablets to possess.

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[1] Jonas Carol has been a chemist with the United States Food and Drug Administration for 21 years, and is chief of the Synthetic Branch of the Division of Pharmaceutical Chemistry. Practically all of his work has been in the analysis of drugs and in the development of methods for their analysis; during the past six years he has been engaged almost exclusively in developing methods for analysis of estrogenic hormones.

Dr. Daniel Banes has been a chemist with the Food and Drug Administration since 1939, specializing in drug analysis since 1940, and doing his chief work since 1948 on the analysis of estrogenic drug preparations.

"Witness Carol used what is known as the infra-red method of analysis in order to double check on the United States Pharmacopoeia, known as U. S. P., method used by the other Government chemists in analyzing samples from the shipments in question. He testified that special procedures were used in an effort to insure complete extraction of the alpha-estradiol from the tablets. Carol stated that his assays disclosed that the amount of alpha-estradiol present per tablet ranged from 23% to 68% of the amount declared on the label.

"Witness Carol also described the results of assays conducted by his associate, Dr. Edward Haenni, upon samples from three of the shipments by means of the U. S. P. method[2] which had been developed by Mr. Carol and his associates. Dr. Haenni's assays indicated that the alpha-estradiol content of the tablets in these three shipments ranged from 32% to 63% of the amount declared on the label. Witness Carol further testified that he had previously tested a number of samples of other commercially prepared alpha-estradiol tablets containing 22 mcgs. by means of the U. S. P. method with successful results.

"Dr. Banes, using the U. S. P. method, assayed samples taken from all five of the shipments in question. He then conducted further special experimental procedures not required by the U. S. P. method, involving additional extractions and the use of a simulated tablet mix, to verify his findings which indicated that the alpha-estradiol content of the tablets ranged from 30% to 73% of the stated amount. Dr. Banes also testified that in the development of the U. S. P. method of assay the developing chemists made certain the method would extract all but a minute portion of the alpha-estradiol in the particular tablets regardless of the ratio of the drug to excipients.

"The appellants do not dispute the fact that less than the purported 22 mcgs. of alpha-estradiol was extracted from the tablets packaged, as measured by the U. S. P. procedure. Their argument is that the U. S. P. method, while perhaps effective in analyzing tablets of greater potency, is inaccurate and unsuitable in extracting alpha-estradiol when combined with the large mass of excipients present in these particular tablets.[3]

"A Mr. Galindo, Vice-President of Crest Laboratories, identified worksheets which purported to indicate meticulous care by Crest in the manufacture of the tablets. He testified that an average of 5% more alpha-estradiol was used than necessary to make a tablet containing 22 mcgs. of the drug. The worksheets were said to show the process of manufacture, step by step, and disclose that the required amount of the drug was placed in the tablets.

"Dr. C. E. P. Jeffreys, consulting chemist and technical director of Truesdail Laboratories, testified that he was asked by Woodard to run an assay on tablets from the shipments in question. Using the U. S. P. procedure, he was able to extract only 8.1 to 9.5 mcgs. of alpha-estradiol from the tablets.[4] Dr. Jeffreys stated that he believed the U. S. P. method of assay did not extract all of the alpha-estradiol present in tablets of such low potency because of adsorption to the solid surface of the excipients, and was thus not a suitable method.[5]

"Dr. Hoyt and Dr. Sobel, associated with the Cedars of Lebanon Hospital, testified to certain experiments conducted at the request of the appellants subsequent to the hearing before the Food and Drug Administration. These experiments, involving assays upon pure estradiol, tablets specially manufactured by Crest to insure the presence of a stated quantity of alpha-estradiol,

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[2] The United States Pharmacopoeia is designated an official compendium by the Federal Food, Drug and Cosmetic Act. 21 U. S. C. A. § 321 (j). U. S. P. XIV first officially recognized alpha-estradiol and provided a method for assay of the drug November 1, 1950. See p. 227. The U. S. P. assay procedure involves a series of extractions in a prescribed method followed by use of a colorimeter to determine the amount of alpha-estradiol extracted.

[3] The Woodard tablets were represented to contain a ratio of 22 parts alpha-estradiol to 324,000 parts of excipients.

[4] Other laboratories retained by the appellants, with the exception of the Adam Laboratories, also were unable to extract and measure the purported 22 mcgs. by means of the U. S. P. method. The Adam Laboratories found no deficiencies in one of a series of assays it conducted and suggested that this discrepancy was caused by some fault in the manufacturing process.

[5] Mr. Don C. Atkins, another witness for the appellants, also testified to a belief that the U. S. P. method was unsuitable, although his testimony tended to suggest that the excipients would cause an artificially high reading of alpha-estradiol.

and tablets containing all the excipients of the usual tablet manufactured by Crest into which Dr. Hoyt and Dr. Sobel personally added certain quantities of alpha-estradiol, were asserted to demonstrate that it was not possible by the use of the U. S. P. method to recover all of the alpha-estradiol when it was held in excipients of the sort that were found in the Woodard tablets.

"The usual rule to be followed in determining the sufficiency of evidence to sustain a judgment is well settled. 'It is not for us to weigh the evidence or to determine the credibility of witnesses. The verdict of a jury must be sustained if there is substantial evidence, taking the view most favorable to the Government, to support it.' Glasser v. United States, 315 U. S. 60, 80 (1942). See Banks v. United States, 147 F. 2d 628 (9th Cir. 1945). However, the appellant strongly urges that the Government's case is founded upon circumstantial evidence, and that therefore the proper test of whether the evidence is sufficient to sustain the judgment depends upon whether all of the substantial evidence is as consistent with a reasonable hypothesis of innocence as with guilt; if it is, the judgment must be reversed. Karn v. United States, 158 F. 2d 568 (9th Cir. 1946); McCoy v. United States, 169 F. 2d 776 (9th Cir. 1948). We find it unneccessary to decide whether the nature of the inference required to logically connect the experimental procedures used by the Government chemists with the factual issue of adulteration requires a characterization of the evidence as circumstantial. Even if we were to concede that the evidence of results obtained in the assays should be regarded as circumstantial, it cannot be said as a matter of law that all the substantial evidence is as consistent with a reasonable hypothesis of innocence as with guilt. The fact that some of the evidence admitted is consistent with innocence is not determinative of the sufficiency of the evidence. Ferris v. United States, 40 F. 2d 837 (9th Cir. 1930). Witness Galindo's worksheets contained a number of discrepancies and omissions which the District Court reasonably could consider on the question of credibility. Although Dr. Hoyt, Dr. Sobel and Dr. Jeffreys testified that their experiments led them to believe the U. S. P. method of assay was unsuitable in these circumstances, the District Court properly could choose to believe instead the testimony of the Government scientists who developed the assay procedure and who testified that the procedure will enable extraction and measurement of alpha-estradiol in tablets of any potency. Substantial evidence is '* * * such relevant evidence as a reasonable mind might accept as adequate to support a conclusion * * *.' N. L. R. B. v. Columbian Co., 306 U. S. 292, 300 (1939). The testimony of witnesses Carol and Banes was substantial and cannot be said to have been as consistent with a reasonable hypothesis of innocence as with guilt.

"Appellants did not attempt to prove the potency of their tablets by some procedure other than the U. S. P. method of assay,[6] they object to the Court's treatment of this as being in the nature of a failure of proof. It is argued that since alpha-estradiol was recognized and the method of assay appeared in an official compendium, U. S. P. XIV, seven months prior to the filing of the information, the determination as to the strength of the drug could be made only according to the official method of assay set forth in the compendium. 21 U. S. C. A. § 351 (b) states that when a drug is recognized in an official compendium the '* * * determination as to its strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium * * *.' Appellants could be held criminally responsible only in the event the drugs were adulterated at the time of their interstate shipment. 21 U. S. C. A. § 331 (a). See Pasadena Research Laboratories v. United States, 169 F. 2d 375, 380 (9th Cir. 1948), cert. den., 335 U. S. 853. Since at the time of such interstate shipments between August 22, 1949, and May 25, 1950, the United States Pharmacopoeia did not officially recognize alpha-estradiol tablets, 21 U. S. C. A. § 351 (b) is inapplicable. The information in fact was based upon 21 U. S. C. A. § 351 (c), which defines adulteration in those situations where § 351 (b) does not apply, *and which is silent as to*

[6] Dr. Hoyt, the appellants' own witness, testified that the alpha-estradiol content of the tablets could have been measured by other assay procedures:

"Q. (The Court). Had they been submitted to you, could you have made an analysis and determined the exact amount of alpha-estradiol in those tablets, using any method you cared to?

"A. I think it could be done—I think perhaps by biological assay it could be done, if not by the U. S. P. method. I am sure it could be done."

the method of determination. There was therefore no restriction upon the method of assay to be employed, although of course the subsequently adopted U. S. P. method was entitled to great weight. As the District Court itself noted, the most direct way for the appellants to have impeached the U. S. P. method of assay would have been for them to have attempted to prove the potency of their tablets by some other assay method.

"Judgment affirmed."

3771. Adulteration and misbranding of vitamin C and vitamin B_1. U. S. v. 330 Vials, etc. (F. D. C. No. 33076. Sample Nos. 17714–L, 17717–L.)

LIBEL FILED: April 16, 1952, Southern District of California.

ALLEGED SHIPMENT: Between January 1944 and January 1950, from Detroit, Mich.

PRODUCT: 330 2-cc. vials of *vitamin C* and 90 10-cc. vials of *vitamin* B_1 at Los Angeles, Calif. Analysis showed that the 330-vial lot contained approximately 85.8 mg. of ascorbic acid per each 2 cc. and that the 90-vial lot contained approximately 76 mg. of vitamin B_1 per each 1 cc.

LABEL, IN PART: "2 cc. size vitamin C Each 2 cc. contains 100 mg. Ascorbic Acid" and "10 cc. size vitamin B_1 (thiamine chloride) Each cc. contains vitamin B_1 100 mg. (equivalent to 33,000 international units)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strengths of the articles differed from those which they purported or were represented to possess.

Misbranding, Section 502 (a), the statements on the label of the *vitamin C* "Each 2 cc. contains 100 mg. Ascorbic Acid" and on the label of the *vitamin* B_1 "Each cc. contains vitamin B_1 100 mg. (equivalent to 33,000 international units)" were false and misleading as applied to the articles, which contained less than those amounts of ascorbic acid and vitamin B_1, respectively.

The articles were adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 8, 1952. Default decree of condemnation and destruction.

3772. Adulteration and misbranding of vitamin B complex. U. S. v. 13 Cases * * *. (F. D. C. No. 33116. Sample No. 31517–L.)

LIBEL FILED: May 2, 1952, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about February 18, 1952, by Delta Laboratories, from Inglewood, Calif.

PRODUCT: 13 cases of *vitamin B complex* at St. Louis, Mo. Analysis showed that the product contained approximately 69 percent of the declared amount of thiamine hydrochloride (vitamin B_1).

LABEL, IN PART: "B Complex with B_{12} & Folic Acid per Vial * * * Thiamine HCL. 10 Mg. * * * Size 10 CC. Units 450 Lot No. 1007."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 10 mg. of thiamine hydrochloride per vial.

Misbranding, Section 502 (a), the label statement "per Vial * * * Thiamine HCL. 10 Mg." was false and misleading as applied to the article, which contained less than 10 mg. of thiamine hydrochloride per vial.

DISPOSITION: May 27, 1952. Default decree of condemnation and destruction.